AF

CASE HM/15-21810/A/PCT/DIV

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Lynn Girolamo	Lynn Girolamo	3/14/06
Type or print name	Signature	Date

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF

WERNER HÖLZL ET AL

APPLICATION NO: 10/750,810

FILED: DECEMBER 31, 2003

FOR: MICROBICIDAL ACTIVE SUBSTANCES

Group Art Unit: 1617

Examiner: B. P. Badio

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

TRANSMITTAL LETTER

Sir:

Enclosed herewith is the Appeal Brief in the above-identified application.

☑ Please charge Deposit Account No. 03-1935 in the amount of $500.00 for payment of the fee. Two additional copies of this paper are here enclosed. The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment, to Account No. 03-1935.

Respectfully submitted,

Kevin T. Mansfield

Kevin T. Mansfield
Agent for Applicants
Reg. No. 31,635

Ciba Specialty Chemicals Corporation
Patent Department
540 White Plains Road
P.O. Box 2005
Tarrytown, NY 10591-9005
(914) 785-7127
KTM/lg
Enc.
Date: March 14, 2006

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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

APPEAL BRIEF

Sir:

This appeal is from the final rejection mailed from the PTO on September 24, 2005.

The Notice of Appeal was mailed to the Patent and Trademark Office with a certificate of first class mailing on January 10, 2006, accompanied by a petition for a 1 month extension of time and a Pre-Appeal Brief Request for Review. Said submissions were dated stamped as received in the PTO on January 17, 2006, making this Brief due on March 17, 2006. Hence this brief is being timely filed.

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(i) REAL PARTY OF INTEREST

The real party of interest is:

Ciba Specialty Chemicals Corp.
P.O. Box 2005
540 White Plains Road
Tarrytown, New York 10591

(ii) RELATED APPEALS AND INTERFERENCES

An Appeal Brief was filed in parent application 09/762,008, wherein the claims were directed to antimicrobial methods of use. The examiner reopened prosecution and ultimately the application matured into U.S. Patent No. 6,689,372 B1.

(iii) STATUS OF THE CLAIMS

Claims 1-10, 14-15 and 17 are cancelled. Claims 11-13 and 17 are withdrawn from consideration. However the examiner has indicated they would be rejoined if personal care product claims 18 and 19 were allowed and they were of the same scope. Claims 18 and 19 are pending and are finally rejected. No claims are allowed.

(iv) STATUS OF AMENDMENTS

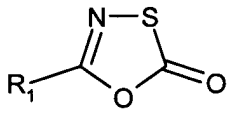
The Response to Final Rejection, mailed to the Patent and Trademark Office on December 13, 2005, only amended claim 11. The Advisory Action mailed on January 6, 2006 indicated said amendment would be entered on filing a Notice of Appeal and Appeal Brief. The claims on appeal are independent claims 18 and 19.

(v) SUMMARY OF THE CLAIMED SUBJECT MATTER

The present invention relates to personal care or oral care preparations comprising selected oxathiazol-2-one derivatives of formula (1) which provide antimicrobial benefits to treated surfaces.

Compounds of formula (1) are disclosed on page 1, lines 3-15 (excluding the title). Some of the compounds embraced by composition claims 18 and 19 are known, but no utility or only an unrelated utility, i.e. as agricultural fungicides, is disclosed.

Independent claims 18 and 19 are directed to personal care or oral care preparations comprising from 0.01 to 15 % by weight, based on the total weight of the composition, of an oxathiazol-2-one derivative of formula

(1) 

wherein

R_1 is C_1-C_{16}alkyl, C_2-C_{16}alkenyl or C_5-C_8cycloalkyl, each unsubstituted or substituted by halogen, -CN, -NO_2, -C=O, -C=S, -NR_2, -OR_3, -SR_4, -SO_2R_5, -$COOR_6$ or by a 1,3,4-oxathiazol-2-one radical;

R_2 and R_3 are each independently of the other hydrogen; C_1-C_5alkyl; C_6-C_{10}aryl, or acyl;

R_4 is hydrogen; C_1-C_5alkyl; or C_6-C_{10}aryl;

R_5 is C_1-C_5alkyl; or C_6-C_{10}aryl; and

R_6 is hydrogen; C_1-C_5alkyl; or C_6-C_{10}aryl,

and a cosmetically or orally tolerable adjuvant, respectively.

Personal care claim 18 is supported by page 5, lines 9-24 of the disclosure, which state:

> The oxathiazolones used according to the invention exhibit a pronounced antimicrobial action, especially against pathogenic gram-positive and gram-negative bacteria and also against bacteria of skin flora, e.g. Corynebacterium xerosis (bacteria that cause body odour), and also against yeasts and moulds. They are therefore especially suitable in the disinfection of the skin and mucosa and also of integumentary appendages (hair), more especially in the disinfection of the hands and of wounds.
>
> They are therefore suitable as antimicrobial active ingredients in personal care preparations, for example shampoos, bath additives, hair-care products, liquid and solid soaps (based on synthetic surfactants and salts of saturated and/or unsaturated fatty acids), lotions and

creams, deodorants, other aqueous or alcoholic solutions, e.g. cleansing solutions for the skin, moist cleansing cloths, oils or powders.

The invention therefore relates also to a personal care preparation comprising at least one compound of formula (1) as well as cosmetically tolerable carriers or adjuvants.

The personal care preparation according to the invention comprises from 0.01 to 15 % by weight, preferably from 0.5 to 10 % by weight, based on the total weight of the composition, of the oxathiazolone compound of formula (1), and cosmetically tolerable adjuvants.

Oral care claim 19 is supported by page 8, lines 20-28 and page 9, lines 1-11 of the disclosure, which state:

The invention relates also to an oral composition, comprising from 0.01 to 15 % by weight, based on the total weight of the composition, of the compound of formula (1), and orally tolerable adjuvants.

Example of an oral composition:
10 % by weight sorbitol
10 % by weight glycerol
15 % by weight ethanol
15 % by weight propylene glycol
0.5 % by weight sodium lauryl sulfate
0.25 % by weight sodium methylcocyl taurate
0.25 % by weight polyoxypropylene/polyoxyethylene block copolymer
0.10 % by weight peppermint flavouring
0.1 to 0.5 % by weight of a compound of formula (1) and
48.6 % by weight water.

The oral composition according to the invention may be, for example, in the form of a gel, a paste, a cream or an aqueous preparation (mouthwash).

The oral composition according to the invention may also comprise compounds that release fluoride ions which are effective against the formation of caries, for example inorganic fluoride

salts, e.g. sodium, potassium, ammonium or calcium fluoride, or organic fluoride salts, e.g. amine fluorides, which are known under the trade name Olafluor.

(vi) GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

The sole issue presented for review is whether claims 18 and 19 are properly rejected under 35 U.S.C. § 103(a) as being unpatentable over Muhlbauer et al. (GB 1,079,348) and Kaminski et al. (U.S. Patent No. 4,115,588) or Lang et al. (U.S. Patent No. 4,772,689) or Blank (U.S. Patent No. 4,847,088) in combination. Claims 18 and 19 are argued separately.

(vii) ARGUMENT

Muhlbauer et al. (GB 1079348) discloses the preparation of certain fungicidally active oxathiazol-2-one derivatives which can be used directly as agricultural fungicides, e.g. to prevent mycelial growth of *Corticium rolfsii* (see page 3, lines 14 to 25 of GB), a soil fungus which may cause root rot. See also the Dissertation Abstract (englisch), publication date January 21, 2002, submitted on December 13, 2005 and listed on a Form PTO 1449, concerning *Corticium rolfsii*. Thus the disclosed preparation mentioned in GB is neither a personal care composition as claimed in claim 18 nor an oral composition as claimed in claim 19, but rather an agricultural composition.

The examiner asserted that that it would have been obvious to use the fungicidal oxathiazol-2-one derivatives of Muhlbauer et al. in the compositions taught by Kaminski et al., Lang et al., and Blank et al. with a reasonable expectation of preventing the contamination and deterioration of said compositions. However, nothing in Muhlbauer et al. suggests that the fungicidal oxathiazol-2-one derivatives therein could be safely applied to a human body, i.e. used in personal care compositions as claimed in claim 18, much less possibly ingested in oral compositions as claimed in claim 19. This is hindsight speculation.

The issue is not merely preventing the contamination and deterioration of compositions in general, it is whether the fungicidal oxathiazol-2-one derivatives of Muhlbauer et al. could **safely** be incorporated into compositions which will provide benefits to a human body when applied in a personal care composition or when administered to a human being in an oral composition. Muhlbauer et al., Kaminski et al., Lang et al., and Blank et al. are all totally silent on this issue.

For *in vitro* testing in Muhlbauer et al., solutions containing 1 part of the active substance and 100 to 1000 parts of acetone were placed in agar dishes. Said solutions were used to distribute the active substance in diluted form upon the agar dish. The acetone can volatilize before contact with the fungal cultures. It is not completely clear from the description, but it is believed that the acetone was evaporated from the agar dish before the contents were contacted with fungal cultures. Otherwise acetone itself might have the effect of preventing mycelial growth of *Corticium rolfsii*. In any event the acetone solution disclosed in Muhlbauer et al. does not teach or suggest the use of the oxathiazol-2-one derivatives in a personal care composition as claimed in claim 18 or an oral composition as claimed in claim 18.

Appellants had urged that the acetone solution described by Muhlbauer et al. could not be applied to a human body, i.e. used in a personal care or oral composition, and enclosed a **2005** material safety data sheet for acetone from a supplier stating that acetone is a target organ and reproductive toxin. Hence, acetone would not be either a cosmetically or orally tolerable adjuvant. In addition, Muhlbauer et al. does not provide any suggestion that the fungicides therein, much less any preparation containing them, in any carrier, could safely be used in any human contact application.

While not rebutting the fact that GB teaches only agricultural fungicides and uses, the examiner cited 2 references, U.S. Patent No. 6,550,080 (Kim et al.) and U.S. Patent No. 5,833,997 (Mahieu et al.), both alleged to teach that acetone is a cosmetically acceptable carrier. It does not appear that it was alleged that either teaches that acetone is an orally acceptable carrier.

U.S. Patent No. 6,550,080 (Kim et al.) is directed to certain fungicidal compounds having a fluorovinyl- or fluoropropenyl-oxyphenyloxime moiety and stereoisomers thereof. Said compounds have a broad spectrum of fungicidal activity against various plant pathogenic fungi (see column 14, line 66, to column 15, line7). Col. 15, lines 20-29 describe suitable carriers for this agricultural use, not personal or oral care use. Acetone is mentioned as one fungicidally acceptable carrier for said agricultural use. There is also no teaching in this reference that the fungicidal compound mentioned is similar or exchangeable with an oxathiazol-2-one derivative, and there is no teaching that a composition containing oxathiazol-2-one derivatives and acetone as carrier may be used in personal care compositions as claimed in claim 18 or oral compositions as claimed in claim 19 and may have an advantageous result. This patent claims **1999** priority documents. Appellants aver it is totally irrelevant to the claimed subject matter.

U.S. Patent No. 5,833,997 (Mahieu et al.) is directed to fluorinated hydrocarbon compounds and their use in cosmetic compositions. It lists acetone as a solvent commonly use in cosmetic compositions in col. 4, line 49, but does not use it at all. This patent issued in 1998 and claims a **1991** priority date.

However, many substances previously thought to be safe are now known not to be. Many years ago the undersigned worked for 3 months in an industrial lab investigating the high temperature vapor phase catalytic air oxidation of benzene to maleic anhydride. The lab operated 24 hours a day and reeked of benzene all the time. But no one was concerned because that was before benzene was recognized to be a human carcinogen. Also, it was not too many years ago that virtually all liquid cough syrups contained 0.5% of chloroform, now also considered a carcinogen, and heroin (!) was originally sold for use in children's cough medicines.

Certainly appellants' current reference refutes the very old teaching of Mahieu et al. concerning the suitability of acetone as a solvent in cosmetic compositions. Hence appellants respectfully submit that Muhlbauer's acetone solutions neither teach nor suggest personal care compositions as claimed in claim 18 or oral compositions as claimed in claim 19 comprising the claimed oxathiazol-2-one derivatives.

Kaminski et al. (U.S. Patent No. 4,115,588) discloses a novel class of N-chloroamino alcohol derivatives which can be used as antibacterial agents in aqueous solutions or in mouthwash, shampoo, soap or other cosmetic preparations (column 17, lines 26 to 48). However the active substance belongs to an entirely different class of chemicals. Without any clear teaching that oxathiazol-2-one derivatives and N-chloroamino alcohol derivatives may be similar or interchangeable with respect to their use in personal care compositions as claimed in claim 18 or oral care compositions as claimed in claim 19, Kaminski et al. constitutes a very remote state of the art. Indeed the teachings of Muhlbauer et al. and Kaminski et al. are so divergent that their combination is improper *per se*.

Lang et al. (U.S. Patent No. 4,772,689) disclose certain quaternary hydroxy-propyl-substituted chitosan derivatives and cosmetic compositions as set forth in column 2, lines 32 to 49. Lang et al. disclose cosmetic (but not oral) compositions; however the active substance belongs to an entirely different class of chemicals. Without any clear teaching that oxathiazol-2-one derivatives and quaternary hydroxy-propyl-substituted chitosan derivatives may be similar or interchangeable with respect to their use in personal care compositions as claimed in claim 18 or oral care compositions as

claimed in claim 19, Lang et al. is also a very remote state of the art, which is not properly combinable with Muhlbauer et al.

Blank et al. (U.S. Patent No. 4,847,088) discloses certain synergistic antimicrobial compositions obtainable by combining a silyl quaternary ammonium compound with an acid as set forth in column 2, lines 40 to 62. Surfaces that can be treated include carpet, fabrics, walls, tables, ceilings, and furnishings, especially paper. See column 9, lines 1-8. Blank et al. does not teach personal care compositions as claimed in claim 18 or oral care compositions as claimed in claim 19. Moreover, without any clear teaching that oxathiazol-2-one derivatives and the combination of a silyl quaternary ammonium compound with an acid may have a similar or interchangeable effect with respect to their use in personal care or oral compositions, Blank et al. is also a very remote state of the art which is not properly combinable with Muhlbauer et al.

Re the combined teachings of the above references, each of the cited references (Muhlbauer et al., Kaminski et al., Lang et al., and Blank et al.) teaches a different specific class of antimicrobial or fungicidally active substances and various uses of compositions containing said substances.

Kaminski et al. and Lang et al. teach that N-chloroamino alcohol derivatives and quaternary hydroxy-propyl-substituted chitosan derivatives, respectively, can be used in cosmetic compositions (Kaminski also includes oral compositions), whereas Muhlbauer et al. and Blank et al. teach that oxathiazol-2-one derivatives and the combination of a silane with an acid, respectively, can be used in agricultural compositions or in soft or hard surface compositions respectively.

There is absolutely no teaching in any of the Kaminski et al., Lang et al., and Blank et al. references that an oxathiazol-2-one derivative may be used in personal care compositions as claimed in claim 18 or oral care compositions as claimed in claim 19. Indeed the teachings of Kaminski et al., Lang et al. and Blank are so divergent from Muhlbauer et al., that their combination with Muhlbauer et al. is improper *per se*.

The fact that certain specific antifungal agents are known to be useful in personal care and/or oral care compositions is not disputed. However, the inference that any antifungal agent, in particular the fungicidal oxathiazol-2-one derivatives of Muhlbauer et al., could be safely applied to a human body, i.e. used in personal care compositions as claimed in claim 18, or incorporated into oral compositions

as claimed in claim 19, where they could possibly be ingested, is totally unwarranted. It is hindsight speculation.

Thus appellants aver that the final rejection of claims 18 and 19 under 35 U.S.C. § 103(a) as being unpatentable over Muhlbauer et al. (GB 1,079,348) and Kaminski et al. (U.S. Patent No. 4,115,588) or Lang et al. (U.S. Patent No. 4,772,689) or Blank (U.S. Patent No. 4,847,088) in combination is seen to be in error as to fact and law and should be REVERSED.

Respectfully submitted,

Kevin T. Mansfield
Agent for Appellants
Reg. No. 31,635

Ciba Specialty Chemicals Corp.
Patent Department
540 White Plains Road
P.O. Box 2005
Tarrytown, NY 10591-9005
(914) 785-7127

KTM\21810DBR

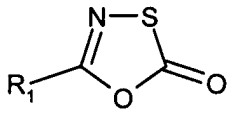
Attachments: Fee Letter; Claims Appendix; Evidence Appendix; Related Proceedings Appendix

(viii) CLAIMS APPENDIX

The claims on appeal are:

18. A personal care preparation, comprising

from 0.01 to 15 % by weight, based on the total weight of the composition, of a compound of formula

(1) 

wherein

R_1 is C_1-C_{16}alkyl, C_2-C_{16}alkenyl or C_5-C_8cycloalkyl, each unsubstituted or substituted by halogen, -CN, $-NO_2$, -C=O, -C=S, $-NR_2$, $-OR_3$, $-SR_4$, $-SO_2R_5$, $-COOR_6$ or by a 1,3,4-oxathiazol-2-one radical;

R_2 and R_3 are each independently of the other hydrogen; C_1-C_5alkyl; C_6-C_{10}aryl, or acyl;

R_4 is hydrogen; C_1-C_5alkyl; or C_6-C_{10}aryl;

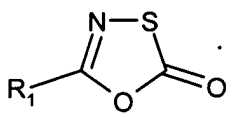
R_5 is C_1-C_5alkyl; or C_6-C_{10}aryl; and

R_6 is hydrogen; C_1-C_5alkyl; or C_6-C_{10}aryl,

and a cosmetically tolerable adjuvant.

19. An oral composition, comprising

from 0.01 to 15 % by weight, based on the total weight of the composition, of a compound of formula

(1) 

wherein

R_1 is C_1-C_{16}alkyl, C_2-C_{16}alkenyl or C_5-C_8cycloalkyl, each unsubstituted or substituted by halogen, -CN, -NO_2, -C=O, -C=S, -NR_2, -OR_3, -SR_4, -SO_2R_5, -$COOR_6$ or by a 1,3,4-oxathiazol-2-one radical;

R_2 and R_3 are each independently of the other hydrogen; C_1-C_5alkyl; C_6-C_{10}aryl, or acyl;

R_4 is hydrogen; C_1-C_5alkyl; or C_6-C_{10}aryl;

R_5 is C_1-C_5alkyl; or C_6-C_{10}aryl; and

R_6 is hydrogen; C_1-C_5alkyl; or C_6-C_{10}aryl,

and an orally tolerable adjuvant.

(ix) EVIDENCE APPENDIX

No evidence is presented by the appellant in the appeal.

(x) RELATED PROCEEDINGS APPENDIX

There are no related proceedings.